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10/705,402	11/10/2003	Satoshi Mizutani	20050/0200486-US0	4520

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EXAMINER	
REICHLE, KARIN M	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,402	MIZUTANI ET AL.	
	Examiner	Art Unit	
	Karin M. Reichle	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6,7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. PCT/JP02/04893.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/18/04, 6-10-04, 4-8-05, 5-4-05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species of minisheet of Figure 7D, the species of attachment of Figure 4D, the species of individual packaging of Figure 27 and the species of multiple packaging of Figure 23E in the reply filed on 6-8-05 is acknowledged.

2. Claims 6-7 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6-8-05.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

For example:

Drawings

4. The drawings are objected to because Figures 29 and 30 should be labeled "PRIOR ART". In Figure 8, 40 should not be underlined. This also applies to numerals 42, 44, 46, 47, 50, 55, 60, 70,.72, 74, 80, 82, 84, 90, 92, 94, 100, 110, 120, 130 and 140 in Figures 9-12, and 14-24. In Figures 16A-C, the edges 66a and b are not shown bonded by dotted pattern embossment as described on page 26, lines 5-6. In Figures 21A-B, the line from 112 should be dashed to denote underlying structure. This also applies to the line from 116 in 21B. The descriptive text

in Figure 24C should be avoided. Figure 27B does not show the finger opening and the package 150 opening pointing in the same direction as described on page 50. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Description

5. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract, line 5.

6. The abstract of the disclosure is objected to because terminology which can be inferred, e.g. "The present invention relates to", and legal terminology, i.e. "comprises", should be avoided. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities: 1) As set forth in MPEP 608.01(o), the meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import. The use of a confusing variety of terms for the same thing should not be permitted. The claims refer to, e.g., an exterior container comprising a package. However, a confusing variety of terms appears to have been used to describe such claim terms, e.g. the exterior container has also been referred to as the "outer vessel" in the title. Each of the claimed features should be referred to consistently by a single term rather than a variety of terms. 2) The Summary of the Invention section, i.e. a description of the claimed invention, and the invention of the claims are not commensurate in scope. See MPEP 608.01(d). 3) On page 18, line 8, "19a" should be after "opening" not "finger". 4) In Figure 13, what is 48? 50 in Figure 14? 70 in Figure 17? 5) How does the exterior container disinfect as set forth on page 28, lines 11-12? 6) On page 29, line 14, "12" should be --112-- and on line 15, after "film", --118-- should be inserted. 7) On page 30, lines 3 and 4, "131" should be --133--.

Appropriate correction is required.

Claim Objections

8. Claims 1-5, 8 and 10-17 are objected to because of the following informalities: In claim 1, lines 4-5, "the whole portion" should be --the entirety--. In claims 1-5, and 12-15, line

1, "individual wrapping body" should be --individually wrapped article system--. In claims 2-5 and 12-15, line 1, "An" should be --The--. Claims 8, 10-11 and 16-17 are considered claims depending from other claims but the preambles thereof are inconsistent with the claims from which they depend. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

9. Claims 1-5, 8 and 10-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, in the last section, Applicant refers to "during manufacturing", "after manufacturing", and "during and after manufacturing". Applicant also refers to "the manufacture". However it is unclear whether such latter terminology and such "manufacturing" are one and the same. Also what does "manufacturing" refer to, i.e. that of the pad, that of the container, that of a combination? Also is Applicant claiming the pad wrapped by the container or not, i.e. compare the preamble to the functional language on lines 2-3 and 4-5? Likewise in claims 8, 10-11 and 16-17, is Applicant claiming a package with at least two individual wrapping bodies or not? For the reasons set forth infra, the claims are indefinite, vague and too broad, see Ex parte Slob, infra. Furthermore, in claims 5 and 14, a positive structural antecedent basis for "said back side sheet" should be set forth.

Claim Language Interpretation

10. "Side area" in claims 5 and 14-15 is defined as set forth on page 8, lines 12-15 of the specification. It is noted that "the neighborhood of the peripheral edge" therein is considered relative absent description of specific dimensions. The terminology "bonded" in claims 4-5 and 10-17 refers to direct and indirect bonding. The terminology "unbonded" in claims 5 and 14-15 refers to direct unbonding. Due to the lack of clarity discussed supra, claim 1 is considered to require an individual wrapping body system comprising a pad capable of the function on lines 2-3 and a container capable of the function on lines 4-5. "Manufacturing" and "the manufacture" will be considered to be one and the same and refer to the manufacture of the pad alone. The language "the number...is suppressed even after a period of six months from the manufacture" is interpreted to mean the number of live microorganisms in the pad is in the range of 0-100 at a point in time just after a six month period from the manufacture of the pad. However, it should be noted that it is claimed the suppression processing is during, after, or during and after the manufacturing of the pad, e.g. "after manufacturing" includes the time of at six months from the manufacture, and "during manufacturing" includes more than six months from manufacture, i.e. the suppression processing can take place any time from the beginning point of manufacture to the six month point from manufacture, and the property of the number of live microorganisms in the pad is claimed to be after a six month period from manufacture of the pad not a six month period after the process of suppression, i.e. the range of the number of live microorganisms in the pad after a six month period from manufacture of the pad is not necessarily the same as such range after a six month period from suppression processing of the pad. Due to the lack of clarity

discussed supra, claims 8, 10-11 and 16-17 are considered to require an exterior container comprising a package capable of the function on lines 1-3 of claims 8 and 16-17.

Claim Rejections - 35 USC § 112, 1st paragraph

11. Claims 1-5, 8 and 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in MPEP 2164.04, the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. While the analysis and conclusion of a lack of enablement are based on the factors discussed in MPEP 2164.01(a) and the evidence as a whole, it is not necessary to discuss each factor in the written rejection. The language should focus on those factors reasons and evidence that lead the examiner to conclude the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

First, what is the claimed invention? As set forth in the only independent claim 1, the invention is considered an individual wrapping body system which comprises an interlabial pad and an individual wrapping container. The interlabial pad is further claimed as having a live microorganism suppressing process applied thereto during manufacture and/or after manufacture and a range of the number of live microorganisms therein, due to the processing, at a point in time just after a period of six months from the manufacture. See Claim Language Interpretation

section supra. The number of microorganism is determined by performing a test set forth in the application. Therefore, the claims also define the invention by processes of manufacture and tests used to determine the number of live organism rather than set forth the specific structure of the end product, i.e. the claims are product by process claims and test characteristic claims.

Second, since the physical characteristics, i.e. the number of live microorganism therein, of the labial pad must be determined, e.g., by a test used to measure such characteristic, the scope of the claims is enabled to the extent the test, i.e. the method and equipment or parameters thereof, measuring such characteristic is described or disclosed.

In the instant application, no test whatsoever, i.e. no method, no equipment, has been disclosed with regard to measurement of the claimed range. The test described on page 49, line 12-page 52, fourth to last line, as best understood, is used to measure the number of live microorganism in the pad after a period of six months from suppression processing of the combination of the pad, an individual wrapping container, an exterior container and an overwrapping film not a test for the measurement of the number of live microorganism in a pad a point after a six month period from manufacture of the pad alone as claimed. Nor is there a specific example of such claimed system including such a pad, i.e. again the disclosure page 49, line 12-page 52, fourth to last line does not exemplify such. Attention is also directed to page 4, lines 19-24 and the abstract which describe the range with respect to manufacture and page 44, line 21-page 45, line 3, as well as the described test, which describe the range with regard to the process of supression. Furthermore, the disclosure of the test on pages 49-52 is unclear. For example, page 51, lines 15-16 refer to "the above-described test". Where is such test described above? On page 51, lines 17-26 some test solution is prepared and a piece of pad exposed

thereto. When does this happen with respect to the manufacture of the pad? The manufacture of the system? The suppression? What is observed and judged? This also applies to the test on page 51, last line-page 52, fourth to last line. On page 52, line 10, it is noted that a certain weight of the pad is tested. How does such weight relate to the entire pad, i.e. how are the results of the test correlated to the entire pad? In other words, the tests used, especially with respect to measurement of the claimed physical characteristics, are not described or disclosed, i.e. enabled, and thus, the claims relying on such are not enabled.

Third, the claims set forth the physical characteristics desired of the pad alone rather than the specific composition of the pad in the end product. Therefore, relying on Ex parte Slob, 157 USPQ 172, such claims could cover any conceivable combination of materials whether presently existing or which might be discovered in the future and which would impart the desired characteristic, i.e. the claims are too broad and indefinite since purport to cover everything having the characteristics regardless of its composition (It should be noted that 35 USC 101 sets forth "Whoever invents or discovers any new and useful...composition of matter...may obtain a patent therefor...title, i.e. does not included compositions that have yet to be invented and discovered.)

Fourth, and similarly, the claims do not set forth anything but a system, i.e. the claims could cover any conceivable pad and container either presently existing or which may discovered in the future. The claims do not set forth that the system is only the pad and container(s), i.e. the claims could cover any conceivable present or future system which includes at least a pad and container(s). The claims do not set forth the specific processes, i.e. the claims could cover any conceivable present or future process. In other words, the claims could cover any conceivable

present or future system end product which includes at the very least a pad and a container(s). Note again Ex parte Slob, supra.

For these reasons and evidence, the examiner concludes the specification fails to teach how to make and use the claimed invention without undue experimentation or that the scope of enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims.

12. Claims 1-5, 8 and 10-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As set forth in MPEP 2163, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not described with sufficient particularity such that one skilled in the art would recognize that the Applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art to or known to one of ordinary skill in the art. Further, as set forth in Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, the lack of adequate written description also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. As discussed in the preceding rejection, the tests which are essential or critical to the selection of the pad have not been disclosed, there is a lack of disclosure or claiming of any specific composition/structure of the pad, there is a lack of disclosure of the

specific composition of the system or end product, i.e. "comprising", and the claims are too broad in that the claims cover any conceivable combination of structure/processes either presently existing or which may be discovered in the future and which may impart the desired characteristics. Therefore, the claimed invention as a whole is not adequately described because the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art to or known to one of ordinary skill in the art and the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. Therefore, one skilled in the art would recognize that the Applicant did not have possession of the claimed invention.

Claim Rejections - 35 USC § 102/103

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-4 and 12-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McFall et al, PCT '689.

See Claim Language Interpretation section supra, Figures 1-5 and 8-9, and page 5, lines 19-27, page 7, first full paragraph, page 7, last full paragraph and page 33, second full paragraph, i.e. the pad is 20, the wrapping container is 50, the permeable side sheet is 42, the back side sheet is 38 and the absorber is 44. The McFall reference teaches all the claimed features except for the range of microorganism, i.e. a test characteristic, as set forth in the last subsection of claim 1. However McFall does teach a processing for the suppression of the number of microorganisms sometime during and/or after the manufacture of the pad but prior to combination with the package 50, see page 29, second full paragraph. Therefore, it is the Examiner's first position that since McFall includes all the claimed structure, processing and capabilities and also expresses the desire for microorganism suppression, that there is reasonable factual basis to conclude that the structure of the McFall also inherently possesses the claimed test characteristic i.e. the claimed range of microorganism in the pad after a period of six months from manufacture thereof when tested according to Applicant's test, as best understood, see discussion supra. In any case, note again that McFall also recognizes the same problem/solution, i.e. need for microorganism suppression, i.e. see portions of McFall cited supra. Therefore, the Examiner's second position, even if the McFall et al reference does not teach the exact range of live microorganism, the general conditions of the claim are disclosed thereby and it is not inventive, i.e. it would be obvious to one of ordinary skill in the art, to discover the optimum or workable ranges, i.e. Applicant's ranges, by routine experimentation, In re Allen. 105 USPQ 233 (CCPA 1955). Finally, the Examiner's third position, claims 1-5, 8 and 10-17 are product by process claims due to the language in the last section of claim 1 and claims 2-3. As set forth in MPEP 2113, even though product by process claims are limited by and defined by the process, i.e. the

processing of microorganism suppression processing and testing for the number of live microorganisms here, determination of patentability is based on the product itself, i.e. the end product. If the product in the product by process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by another process. As already discussed supra, since the number of live microorganisms of the pad of the end product, i.e. the system, is unknown, at most, the end product of claims 1-3, is known to be a system of a pad and container as discussed above. Since such a product appears to be the same or similar to that of McFall et al the claims are considered unpatentable.

15. Claims 5 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFall et al in view of Wierlacher PCT '096.

See discussion of claims supra and the Claim Language Interpretation section. Also, see, e.g., page 32, last full paragraph of McFall et al. Therefore, McFall et al teaches that the handling aid for attaching the pad directly to the body may be a loop but does not disclose the specifics thereof, i.e. a mini sheet with bonded and unbonded areas. However, see Wierlacher at, e.g., Figures and page 17, line 30-page 18, line 30 and page 20, lines 19-24. To substitute the loop handling aid for attaching the pad directly to the body of Weirlacher for that of McFall would be obvious, In re Siebentritt, 54 CCPA 1083 (two equivalents are interchangeable for their desired function, express suggestion of desirability of substitution not need to render such substitution obvious). In so doing the prior art combination teaches the structure claimed of the minisheet in the claims.

16. Claims 8, 10-11 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFall in view of Brisebois et al.

The claims require an exterior container and the specifics thereof which container is capable of packaging at least two of the individual wrapping body systems, see Claim Language Interpretation section supra. McFall does not teach such an exterior container. However, it is well know to package a plurality of individual wrapping body systems together in a cardboard box or other container for efficient consumer sale. See, for example, Brisebois et al at col. 1, lines 26-42. It is also well known that such boxes or other containers include a main body and lid or flap which lid or flap is continuous with the main body but bonded to the main body to form the package, see, for example, Figures 1 and 2 of Brisebois. Therefore, to employ an exterior container having the structure claimed in claims 8, 10-11 and 16-17 capable of packaging at least two individual wrapping body systems as taught by McFall would have been obvious to one of ordinary skill in the art in view of the recognition that such a container is well know in combination with such systems for efficient consumer sales thereof and the desire of efficient consumer sales with respect to any system intended for sale such as that taught by McFall.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Schwartz can be reached on (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR
June 23, 2005